



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Subhashis Banerjee et al.

Serial No.: 10/623,035

ART UNIT: 1643

Filed: July 18, 2003

EXAMINER: David J. Blanchard

Entitled: : TREATMENT OF PAIN USING  
TNFALPHA INHIBITORS

Attorney Docket No.: BBC-206

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

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December 5, 2005  
Date

Daphne Miller  
Daphne Miller

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §§ 1.56, 1.97 AND 1.98**

Sir/Madam:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 for the above-identified application. Applicants makes the following publications of record in the above-identified application.

U.S. Patent Documents

Salfeld et al., July 18, 2000, U.S. Patent No. 6,090,382

Salfeld et al., July 10, 2001, U.S. Patent No. 6,258,562

Salfeld et al., January 21, 2003, U.S. Patent No. 6,509,015

#### Foreign Patent Documents

Kempeni et al., December 19, 2002, WO 02/100330  
Fischkoff et al., January 15, 2004, WO 2004/004633  
Krause et al., February 26, 2004, WO 2004/016286  
Kaymakcalan et al., May 6, 2004, WO 2004/037205  
Salfeld et al., August 14, 1997, WO 97/29131

#### Other Publications

Aloe et al., *Psychopharmacology (Berl)*. 1997 Dec; 134(3): 287-292.  
Bennett and Xie, (1988) *Pain*. 33: 87-107.  
Coelho et al., *Am J Physiol Gastrointest Liver Physiol*. 2000 Oct; 279(4): G781-G790.  
Coelho et al., *Brain Res Bull*. 2000 Jun; 52(3): 223-228.  
Cunha et al., *Br J Pharmacol*. 1992 Nov., 107(3): 660-664.  
Empl et al., *Neurology*. 2001 May 22; 56(10): 1371-1377.  
Huygen et al., *Mediators Inflamm*. 2002 Feb; 11(1): 47-51.  
Ignatowski et al., *Brain Res*. 1999 Sep 11; 841(1-2): 70-77.  
Kim and Chung, (1992) *Pain* 50: 355-363  
Lindenlaub and Sommer (2003) *Acta Neuropathol (Berl)*. 105:593  
Lindenlaub et al., *Brain Res*. 2000 Jun 2; 866(1-2): 15-22.  
Myers, *Regional Anesthesia* (1995) 20:173-184  
Old, L. *Science* (1985) 230: 630-632  
Olmarker et al., *Spine*. 2001 Apr 15; 26(8): 863-869.  
Parada et al., *Eur J Neurosci*. 2003 May; 17(9): 1847-1852.  
Sagara et al., *Diabetologia*. 1996 Mar; 39(3): 263-269.  
Schafers et al., *Neurosci Lett*. 2001 Sep 14; 310(2-3): 113-116.  
Schafers et al., *J Neurosci*. 2003 Apr 1; 23(7): 3028-3038.  
Sommer et al., *Brain Res*. 2001 Sep 14; 913(1): 86-89.  
Sommer et al., *J Peripher Nerv Syst*. 2001 Jun; 6(2): 67-72.  
Sommer et al., *Exp Neurol*. 1998 May; 151(1):138-142.  
Sommer, C., *Schmerz* (1999) 13(5): 315-23.  
Sorkin et al., *Neuroscience*. 1997 Nov; 81(1): 255-262.  
Watkins et al., *Brain Res*. 1994 Aug 15; 654(1): 15-26.  
Zimmermann, *Eur J Pharmacol*. 2001 Oct 19; 429(1-3): 23-37.

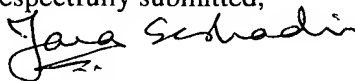
Form PTO-1449 listing each of these documents and photocopies of each document are enclosed herewith for the Examiner's convenience.

This paper is being mailed before the mailing of a first Office action. Pursuant to 37 CFR §1.97(b)(4), no fee is required with this submission.

Applicant does not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Tara Seshadri". The signature is fluid and cursive, with a horizontal line under the first name.

Tara Seshadri, Ph.D.  
Agent for Applicant  
Registration No. 48,591  
Abbott Bioresearch Center  
100 Research Drive  
Worcester, MA 01605-4314  
Telephone: (508) 688-8058  
Telefax: (508) 688-8110



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of	4
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Application Number

10/623.035
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Filing Date

July 18, 2003
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First Named Inventor

S. Banerjee

Art Unit

1643

Examiner Name \_\_\_\_\_

David J. Blanchard
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Attorney Docket Number

BBC-206

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		Application Number	10/623,035		
		Filing Date	July 18, 2003		
		First Named Inventor	S. Banerjee		
		Art Unit	1643		
		Examiner Name	David J. Blanchard		
Sheet	2	of	4	Attorney Docket Number	BBC-206

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Aloe et al., "Role of TNF-alpha but not NGF in murine hyperalgesia induced by parasitic infection". Psychopharmacology (Berl). 1997 Dec; 134(3): 287-292.	
		Bennett and Xie, "A peripheral mononeuropathy in rat that produces disorders of pain sensation like those seen in man". (1988) Pain. 33: 87-107.	
		Coelho et al., "Systemic lipopolysaccharide influences rectal sensitivity in rats: role of mast cells, cytokines, and vagus nerve". Am J Physiol Gastrointest Liver Physiol. 2000 Oct; 279(4): G781-G790.	
		Coelho et al., "Brain interleukin-1 $\beta$ and tumor necrosis factor- $\alpha$ are involved in lipopolysaccharide-induced delayed rectal allodynia in awake rats". Brain Res Bull 2000 June, 52(3): 223-228.	
		Cunha et al., "The pivotal role of tumour necrosis factor alpha in the development of inflammatory hyperalgesia." Br J Pharmacol. 1992 Nov., 107(3): 660-664.	
		Empl et al., Neurology. "TNF-alpha expression in painful and nonpainful neuropathies." 2001 May 22; 56(10): 1371-1377.	
		Huygen et al., "Evidence for local inflammation in complex regional pain syndrome type 1." Mediators Inflamm. 2002 Feb;11(1): 47-51.	
		Ignatowski et al., "Brain-derived TNFalpha mediates neuropathic pain." Brain Res. 1999 Sep 11; 841(1-2): 70-77.	
		Kim and Chung, "An experimental model for peripheral neuropathy produced by segmental spinal nerve ligation in the rat." (1992) Pain 50: 355-363	
		Lindenlaub and Sommer, "Cytokines in sural nerve biopsies from inflammatory and non-inflammatory neuropathies." (2003) Acta Neuropathol (Berl). 105:593	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		Myers, R., "The Pathogenesis of Neuropathic Pain." Regional Anesthesia (1995) 20(3):173-184.	
		Old, L., "Tumor Necrosis Factor (TNF)." (1985) Science 230: 630-632	
		Olmarker et al., "Selective Inhibition of Tumor Necrosis Factor- $\alpha$ Prevents Nucleus Pulposus-Induced Thrombus Formation, Intraneural Edema, and Reduction of Nerve Conduction Velocity." Spine. 2001 Apr 15; 26(8): 863-869.	
		Parada et al., "Tumor necrosis factor receptor type-1 in sensory neurons contributes to induction of chronic enhancement of inflammatory hyperalgesia in rat." Eur J Neurosci. 2003 May; 17(9): 1847-1852.	
		Sagara et al., "Inhibition of development of peripheral neuropathy in streptozotocin-induced diabetic rats with N-acetylcysteine." Diabetologia. 1996 Mar; 39(3): 263-269.	
		Schafers et al., "Combined epineurial therapy with neutralizing antibodies to tumor necrosis factor- $\alpha$ and interleukin-1 receptor has an additive effect in reducing neuropathic pain in mice." Neurosci Lett. 2001 Sep 14; 310(2-3): 113-116.	
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		Sommer et al., "Anti-TNF-neutralizing antibodies reduce pain-related behavior in two different mouse models of painful mononeuropathy." Brain Res. 2001 Sep 14; 913(1): 86-89.	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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		Sommer, C. "Animal studies on neuropathic pain: the role of cytokines and cytokine receptors in pathogenesis and therapy." Schmerz . (1999) 13(5): 315-323.	
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